



General

Guideline Title

Clinical practice guidelines for antimicrobial prophylaxis in surgery.

Bibliographic Source(s)

Bratzler DW, Dellinger EP, Olsen KM, Perl TM, Auwaerter PG, Bolon MK, Fish DN, Napolitano LM, Sawyer RG, Slain D, Steinberg JP, Weinstein RA. Clinical practice guidelines for antimicrobial prophylaxis in surgery. Am J Health Syst Pharm. 2013 Feb 1;70(3):195-283. [1075 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Society of Health-System Pharmacists. ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999 Sep 15;56(18):1839-88.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [May 12, 2016 – Fluoroquinolone Antibacterial Drugs](#) : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

Adult and pediatric dosages are included in Table 1 of the original guideline document. Recommendations for the selection of prophylactic antimicrobials for various surgical procedures are provided in Table 2 of the original guideline document.

Summary of Key Updates

These guidelines reflect substantial changes from the guidelines published in 1999. Highlights of those changes are outlined here.

Preoperative-dose Timing

The optimal time for administration of preoperative doses is within 60 minutes before surgical incision. This is a more-specific time frame than the previously recommended time, which was "at induction of anesthesia." Some agents, such as fluoroquinolones and vancomycin, require administration over one to two hours; therefore, the administration of these agents should begin within 120 minutes before surgical incision.

Selection and Dosing

Information is included regarding the approach to weight-based dosing in obese patients and the need for repeat doses during prolonged procedures. Obesity has been linked to an increased risk for surgical-site infection (SSI). The pharmacokinetics of drugs may be altered in obese patients, so dosage adjustments based on body weight may be warranted in these patients. For all patients, intraoperative redosing is needed to ensure adequate serum and tissue concentrations of the antimicrobial if the duration of the procedure exceeds two half-lives of the drug or there is excessive blood loss during the procedure (see Table 1 in original guideline document). Recommendations for selection of antimicrobial agents for specific surgical procedures and alternative agents (e.g., for patients with allergies to β -lactam antimicrobials) are provided in Table 2 in the original guideline document.

Duration of Prophylaxis

New recommendations for a shortened post-operative course of antimicrobials involving a single dose or continuation for less than 24 hours are provided. Further clarity on the lack of need for postoperative antimicrobial prophylaxis based on the presence of indwelling drains and intravascular catheters is included.

Common Principles

A section addressing concepts that apply to all types of surgical procedures has been added. Expanded and new recommendations are provided for plastic, urology, cardiac, and thoracic procedures, as well as clarity on prophylaxis when implantable devices are inserted. The latest information on the use of mupirocin and on the role of vancomycin in surgical prophylaxis is summarized in these updated guidelines.

See the original guideline document for a discussion of common principles; common surgical pathogens; drug administration; topical administration of irrigations, pastes, and washes; pre-operative screening and decolonization; and future research.

Cardiac Procedures

For patients undergoing cardiac procedures, the recommended regimen is a single pre-incision dose of cefazolin or cefuroxime with appropriate intraoperative redosing (see Table 2 in original guideline document). Currently, there is no evidence to support continuing prophylaxis until all drains and indwelling catheters are removed. Clindamycin or vancomycin is an acceptable alternative in patients with a documented β -lactam allergy. Vancomycin should be used for prophylaxis in patients known to be colonized with methicillin-resistant *Staphylococcus aureus* (MRSA). If organizational SSI surveillance shows that gram-negative organisms cause infections for patients undergoing these operations, practitioners should combine clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, aminoglycoside, or single dose fluoroquinolone if the patient is β -lactam allergic). Mupirocin should be given intranasally to all patients with documented *S. aureus* colonization. (Strength of evidence for prophylaxis = A.)

Cardiac Device Insertion Procedures

A single dose of cefazolin or cefuroxime is recommended for device implantation or generator replacement in a permanent pacemaker, implantable cardioverter defibrillator, or cardiac resynchronization device. (Strength of evidence for prophylaxis = A.) There is limited evidence to make specific recommendations for ventricular assist devices (VADs), and each practice should tailor protocols based on pathogen prevalence and local susceptibility profiles. Clindamycin or vancomycin is an acceptable alternative in patients with a documented β -lactam allergy. Vancomycin should be considered for prophylaxis in patients known to be colonized with MRSA.

Thoracic Procedures

In patients undergoing thoracic procedures, a single dose of cefazolin or ampicillin-sulbactam is recommended (see Appendix B in original guideline document). Clindamycin or vancomycin is an acceptable alternative in patients with a documented β -lactam allergy. Vancomycin should be used for prophylaxis in patients known to be colonized with MRSA. If organizational SSI surveillance shows that gram-negative organisms are associated with infections during these operations or if there is risk of gram-negative contamination of the surgical site, practitioners should combine clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, aminoglycoside, or single-dose fluoroquinolone if the patient is β -lactam allergic). (Strength of evidence for prophylaxis for video-assisted thoracoscopic surgery [VATS] = C;

strength of evidence for prophylaxis for other thoracic procedures = A.)

Gastroduodenal Procedures

Antimicrobial prophylaxis in gastroduodenal procedures should be considered for patients at highest risk for postoperative infections, including risk factors such as increased gastric pH (e.g., patients receiving acid-suppression therapy), gastroduodenal perforation, decreased gastric motility, gastric outlet obstruction, gastric bleeding, morbid obesity, American Society of Anesthesiologists (ASA) classification of ≥ 3 , and cancer. A single dose of cefazolin is recommended in procedures during which the lumen of the intestinal tract is entered (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = A.) A single dose of cefazolin is recommended in clean procedures, such as highly selective vagotomy, and antireflux procedures only in patients at high risk of postoperative infection due to the presence of the above risk factors. (Strength of evidence for prophylaxis = C.) Alternative regimens for patients with β -lactam allergy include clindamycin or vancomycin plus gentamicin, aztreonam, or a fluoroquinolone. Higher doses of antimicrobials are uniformly recommended in morbidly obese patients undergoing bariatric procedures. Higher doses of antimicrobials should be considered in significantly overweight patients undergoing gastroduodenal and endoscopic procedures.

Biliary Tract Procedures

A single dose of cefazolin should be administered in patients undergoing open biliary tract procedures (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = A.) Alternatives include ampicillin–sulbactam and other cephalosporins (cefotetan, cefoxitin, and ceftriaxone). Alternative regimens for patients with β -lactam allergy include clindamycin or vancomycin plus gentamicin, aztreonam, or a fluoroquinolone; or metronidazole plus gentamicin or a fluoroquinolone. Antimicrobial prophylaxis is not necessary in low-risk patients undergoing elective laparoscopic cholecystectomies. (Strength of evidence against prophylaxis for low-risk patients = A.) Antimicrobial prophylaxis is recommended in patients undergoing laparoscopic cholecystectomy who have an increased risk of infectious complications. Risk factors include performance of emergency procedures, diabetes, anticipated procedure duration exceeding 120 minutes, risk of intraoperative gallbladder rupture, age of >70 years, open cholecystectomy, risk of conversion of laparoscopic to open cholecystectomy, American Society of Anesthesiologists (ASA) classification of ≥ 3 , episode of biliary colic within 30 days before the procedure, reintervention in less than a month for noninfectious complications of prior biliary operation, acute cholecystitis, anticipated bile spillage, jaundice, pregnancy, nonfunctioning gallbladder, and immunosuppression. Because some of these risk factors cannot be determined before the surgical intervention, it may be reasonable to give a single dose of antimicrobial prophylaxis to all patients undergoing laparoscopic cholecystectomy. (Strength of evidence for prophylaxis for high-risk patients = A.)

Appendectomy Procedures

For uncomplicated appendicitis, the recommended regimen is a single dose of a cephalosporin with anaerobic activity (cefoxitin or cefotetan) or a single dose of a first-generation cephalosporin (cefazolin) plus metronidazole (see Table 2 in original guideline document). For β -lactam-allergic patients, alternative regimens include (1) clindamycin plus gentamicin, aztreonam, or a fluoroquinolone and (2) metronidazole plus gentamicin or a fluoroquinolone (ciprofloxacin or levofloxacin). (Strength of evidence for prophylaxis = A.)

Small Intestine Procedures

For small bowel surgery without obstruction, the recommended regimen is a first generation cephalosporin (cefazolin) (see Table 2 in original guideline document). For small bowel surgery with intestinal obstruction, the recommended regimen is a cephalosporin with anaerobic activity (cefoxitin or cefotetan) or the combination of a first-generation cephalosporin (cefazolin) plus metronidazole. For β -lactam-allergic patients, alternative regimens include (1) clindamycin plus gentamicin, aztreonam, or a fluoroquinolone and (2) metronidazole plus gentamicin or a fluoroquinolone (ciprofloxacin or levofloxacin). (Strength of evidence for prophylaxis = C.)

Hernia Repair Procedures (Hernioplasty and Herniorrhaphy)

For hernioplasty and herniorrhaphy, the recommended regimen is a single dose of a first-generation cephalosporin (cefazolin) (see Table 2 in original guideline document). For patients known to be colonized with MRSA, it is reasonable to add a single preoperative dose of vancomycin to the recommended agent. For β -lactam allergic patients, alternative regimens include clindamycin and vancomycin. (Strength of evidence for prophylaxis = A.)

Colorectal Procedures

A single dose of second-generation cephalosporin with both aerobic and anaerobic activities (cefoxitin or cefotetan) or cefazolin plus metronidazole is recommended for colon procedures (see Table 2 in original guideline document). In institutions where there is increasing resistance to first- and second-generation cephalosporins among gram-negative isolates from SSIs, the expert panel recommends a single dose of ceftriaxone plus metronidazole over routine use of carbapenems. An alternative regimen is ampicillin–sulbactam. In most patients, mechanical

bowel preparation (MBP) combined with a combination of oral neomycin sulfate plus oral erythromycin base or oral neomycin sulfate plus oral metronidazole should be given in addition to intravenous (i.v.) prophylaxis. The oral antimicrobial should be given as three doses over approximately 10 hours the afternoon and evening before the operation and after the MBP. Alternative for patients with β -lactam allergies include (1) clindamycin plus an aminoglycoside, aztreonam, or a fluoroquinolone and (2) metronidazole plus an aminoglycoside or a fluoroquinolone. Metronidazole plus aztreonam is not recommended as an alternative because this combination has no aerobic gram-positive activity (Morris et al., 1990). (Strength of evidence for prophylaxis = A.)

Head and Neck Procedures

Clean Procedures

Antimicrobial prophylaxis is not required in patients undergoing clean surgical procedures of the head and neck. If there is placement of prosthetic material, a preoperative dose of cefazolin or cefuroxime is reasonable, though there are few data supporting the efficacy of prophylaxis in this setting (see Table 2 in original guideline document). A reasonable alternative for patients with β -lactam allergies is clindamycin. (Strength of evidence against prophylaxis without prosthesis placement = B; Strength of evidence for prophylaxis with prosthesis placement = C.)

Clean-contaminated Procedures

Antimicrobial prophylaxis has not been shown to benefit patients undergoing tonsillectomy or functional endoscopic sinus procedures. The preferred regimens for patients undergoing other clean-contaminated head and neck procedures are (1) cefazolin or cefuroxime plus metronidazole and (2) ampicillin–sulbactam. Clindamycin is a reasonable alternative in patients with a documented β -lactam allergy. The addition of an aminoglycoside to clindamycin may be appropriate when there is an increased likelihood of gram-negative contamination of the surgical site. (Strength of evidence for prophylaxis in cancer surgery patients = A; Strength of evidence for prophylaxis for other clean-contaminated procedures except tonsillectomy and functional endoscopic sinus procedures = B.)

Neurosurgery Procedures

A single dose of cefazolin is recommended for patients undergoing clean neurosurgical procedures, cerebrospinal fluid (CSF)-shunting procedures, or intrathecal pump placement (see Table 2 in original guideline document). Clindamycin or vancomycin should be reserved as an alternative agent for patients with a documented β -lactam allergy (vancomycin for MRSA-colonized patients). (Strength of evidence for prophylaxis = A.)

Cesarean Delivery Procedures

The recommended regimen for all women undergoing cesarean delivery is a single dose of cefazolin administered before surgical incision (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = A.) For patients with β -lactam allergies, an alternative regimen is clindamycin plus gentamicin.

Hysterectomy Procedures

The recommended regimen for women undergoing vaginal or abdominal hysterectomy, using an open or laparoscopic approach, is a single dose of cefazolin (see Table 2 in original guideline document). Cefoxitin, cefotetan, or ampicillin–sulbactam may also be used. Alternative agents for patients with a β -lactam allergy include (1) either clindamycin or vancomycin plus an aminoglycoside, aztreonam, or a fluoroquinolone and (2) metronidazole plus an aminoglycoside or a fluoroquinolone. (Strength of evidence for prophylaxis = A.)

Ophthalmic Procedures

Due to the lack of robust data from trials, specific recommendations cannot be made regarding choice, route, or duration of prophylaxis. As a general principle, the antimicrobial prophylaxis regimens used in ophthalmic procedures should provide coverage against common ocular pathogens, including *Staphylococcus* species and gram-negative organisms, particularly *Pseudomonas* species. Preoperative antisepsis with povidone–iodine is recommended, based on available evidence. Appropriate topical antimicrobials include commercially available neomycin–polymyxin B–gramicidin solution or fluoroquinolones (particularly fourth-generation agents) given as one drop every 5–15 minutes for five doses within the hour before the start of the procedure (see Table 2 in original guideline document). The addition of subconjunctival cefazolin 100 mg or intracameral cefazolin 1–2.5 mg or cefuroxime 1 mg at the end of the procedure is optional. While some data have shown that intracameral antimicrobials may be more effective than subconjunctival antimicrobials, there are no commercially available antimicrobials approved for these routes of administration. (Strength of evidence for prophylaxis = B.)

Orthopedic Procedures

Antimicrobial prophylaxis is not recommended for patients undergoing clean orthopedic procedures, including knee, hand, and foot procedures; arthroscopy; and other procedures without instrumentation or implantation of foreign materials. (Strength of evidence against prophylaxis = C.) If

the potential for implantation of foreign materials is unknown, the procedure should be treated as with implantation.

Spinal Procedures with and Without Instrumentation

Antimicrobial prophylaxis is recommended for orthopedic spinal procedures with and without instrumentation. The recommended regimen is cefazolin (see Table 2 in original guideline document). (Strength of evidence for prophylaxis in orthopedic spinal procedures = A.) Clindamycin and vancomycin should be reserved as alternative agents as described in the Common Principles section in the original guideline document. If there are surveillance data showing that gram-negative organisms are a cause of SSIs for the procedure, practitioners may consider combining clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, gentamicin, or single-dose fluoroquinolone if the patient is β -lactam allergic). Mupirocin should be given intranasally to all patients known to be colonized with *S. aureus*.

Hip Fracture Repair

The recommended regimen in hip fracture repair or other orthopedic procedures involving internal fixation is cefazolin. Clindamycin and vancomycin should be reserved as alternative agents, as described in the Common Principles section in the original guideline document. If there are surveillance data showing that gram-negative organisms are a cause of SSIs for the procedure, practitioners may consider combining clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, gentamicin, or single-dose fluoroquinolone if the patient is β -lactam allergic). Mupirocin should be given intranasally to all patients with documented colonization with *S. aureus*. (Strength of evidence for prophylaxis = A.)

Total Joint Replacement

The recommended regimen for patients undergoing total hip, elbow, knee, ankle, or shoulder replacement is cefazolin. Clindamycin and vancomycin should be reserved as alternative agents, as described in the Common Principles section in the original guideline document. If there are any surveillance data showing that gram-negative organisms are a cause of SSIs for the procedure, practitioners may consider combining clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, gentamicin, or a single dose fluoroquinolone if the patient is β -lactam allergic). Mupirocin should be given intranasally to all patients with documented colonization with *S. aureus*. (Strength of evidence for prophylaxis = A.)

Urologic Procedures

No antimicrobial prophylaxis is recommended for clean urologic procedures in patients without risk factors for postoperative infections. Patients with preoperative bacteriuria or urinary tract infection (UTI) should be treated before the procedure, when possible, to reduce the risk of postoperative infection. For patients undergoing lower urinary tract instrumentation with risk factors for infection, the use of a fluoroquinolone or trimethoprim–sulfamethoxazole (oral or i.v.) or cefazolin (i.v. or intramuscular) is recommended (see Table 2 in original guideline document). For patients undergoing clean urologic procedures without entry into the urinary tract, cefazolin is recommended, with vancomycin or clindamycin as an alternative for those patients allergic to β -lactam antimicrobials. For patients undergoing clean urologic procedures with entry into the urinary tract, cefazolin is recommended, with alternative antimicrobials to include a fluoroquinolone, the combination of an aminoglycoside plus metronidazole, or an aminoglycoside plus clindamycin. For clean-contaminated procedures of the urinary tract (often entering the gastrointestinal tract), antimicrobials as recommended for elective colorectal surgery are recommended. This would generally include the combination of cefazolin with or without metronidazole, cefoxitin, or, for patients with β -lactam allergy, a combination of either a fluoroquinolone or aminoglycoside given with either metronidazole or clindamycin. The medical literature does not support continuing antimicrobial prophylaxis until urinary catheters have been removed. See the colorectal procedures section above for recommendations pertaining to procedures entering the gastrointestinal tract. (Strength of evidence for prophylaxis = A.)

Vascular Procedures

The recommended regimen for patients undergoing vascular procedures associated with a higher risk of infection, including implantation of prosthetic material, is cefazolin (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = A.) Clindamycin and vancomycin should be reserved as alternative agents as described in the Common Principles section in the original guideline document. If there are surveillance data showing that gram-negative organisms are a cause of SSIs for the procedure, practitioners may consider combining clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, gentamicin, or single-dose fluoroquinolone if the patient is β -lactam allergic), due to the potential for gastrointestinal flora exposure.

Heart, Lung, and Heart–Lung Transplantation

Based on data from other types of cardiothoracic procedures, all adult patients undergoing lung transplantation should receive antimicrobial prophylaxis, because of the high risk of infection. Patients with negative pretransplantation cultures should receive antimicrobial prophylaxis as appropriate for other types of cardiothoracic procedures. The recommended regimen is a single dose of cefazolin (see Table 2 in original guideline

document). There is no evidence to support continuing prophylaxis until chest and mediastinal drainage tubes are removed. Alternatives include vancomycin with or without gentamicin, aztreonam, and a single fluoroquinolone dose. (Strength of evidence for prophylaxis = A.) The optimal duration of antimicrobial prophylaxis for patients who do not have their chest primarily closed is unclear. No recommendation is made for these patients. The prophylactic regimen should be modified to provide coverage against any potential pathogens, including gram-negative (e.g., *P. aeruginosa*) and fungal organisms, isolated from the donor lung or the recipient pretransplantation. The prophylactic regimen may also include antifungal agents for *Candida* and *Aspergillus* species based on patient risk factors for infection (e.g., cystic fibrosis) and colonization, pretransplantation and posttransplantation cultures, and local fungus epidemiology. Patients undergoing lung transplantation for cystic fibrosis should receive treatment for at least seven days with antimicrobials selected according to pretransplantation culture and susceptibility results. (Strength of evidence for prophylaxis = B.)

Liver Transplantation

The recommended agents for patients undergoing liver transplantation are (1) piperacillin–tazobactam and (2) cefotaxime plus ampicillin (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = B.) For patients who are allergic to β -lactam antimicrobials, clindamycin or vancomycin given in combination with gentamicin, aztreonam, or a fluoroquinolone is a reasonable alternative. The duration of prophylaxis should be restricted to 24 hours or less. For patients at high risk of *Candida* infection, fluconazole adjusted for renal function may be considered. (Strength of evidence for prophylaxis = B.)

Pancreas and Pancreas–Kidney Transplantation

The recommended regimen for patients undergoing pancreas or simultaneous pancreas–kidney (SPK) transplantation is cefazolin (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = A.) For patients who are allergic to β -lactam antimicrobials, clindamycin or vancomycin given in combination with gentamicin, aztreonam, or a fluoroquinolone is a reasonable alternative. The duration of prophylaxis should be restricted to 24 hours or less. The use of aminoglycosides in combination with other nephrotoxic drugs may result in renal dysfunction and should be avoided unless alternatives are contraindicated. (Strength of evidence for prophylaxis = C.) For patients at high risk of *Candida* infection, fluconazole adjusted for renal function may be considered.

Kidney Transplantation

The recommended agent for patients undergoing kidney transplantation is cefazolin (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = A.) For patients who are allergic to β -lactam antimicrobials, clindamycin or vancomycin given in combination with gentamicin, aztreonam, or a fluoroquinolone is a reasonable alternative. The duration of prophylaxis should be restricted to 24 hours or less. The use of aminoglycosides in combination with other nephrotoxic drugs may result in renal dysfunction and should be avoided unless alternatives are contraindicated. (Strength of evidence for prophylaxis = C.) For patients at high risk of *Candida* infection, fluconazole adjusted for renal function may be considered.

Plastic Surgery and Breast Procedures

Antimicrobial prophylaxis is not recommended for most clean procedures in patients without additional postoperative infection risk factors as listed in the Common Principles section and the background discussion of the plastic surgery and breast procedures section in the original guideline document. Although no studies have demonstrated antimicrobial efficacy in these procedures, expert opinion recommends that patients with risk factors undergoing clean plastic procedures receive antimicrobial prophylaxis. The recommendation for clean-contaminated procedures, breast cancer procedures, and clean procedures with other risk factors is a single dose of cefazolin or ampicillin–sulbactam (see Table 2 in original guideline document). (Strength of evidence for prophylaxis = C.) Alternative agents for patients with β -lactam allergy include clindamycin and vancomycin. If there are surveillance data showing that gram-negative organisms cause SSIs for the procedure, the practitioner may consider combining clindamycin or vancomycin with another agent (cefazolin if the patient is not β -lactam allergic; aztreonam, gentamicin, or single-dose fluoroquinolone if the patient is β -lactam allergic). Postoperative duration of antimicrobial prophylaxis should be limited to less than 24 hours, regardless of the presence of indwelling catheters or drains.

Definitions:

Levels of Evidence

The strength of evidence represents only support for or against prophylaxis and does not apply to the antimicrobial choice, dose, or dosage regimen. Studies supporting the recommendations for the use of an antimicrobial were classified as follows:

- Level I (evidence from large, well conducted, randomized, controlled clinical trials or a meta-analysis)
- Level II (evidence from small, well conducted, randomized, controlled clinical trials)
- Level III (evidence from well conducted cohort studies)

- Level IV (evidence from well conducted case–control studies)
- Level V (evidence from uncontrolled studies that were not well conducted)
- Level VI (conflicting evidence that tends to favor the recommendation)
- Level VII (expert opinion or data extrapolated from evidence for general principles and other procedures)

Strength of Recommendations

Each recommendation was categorized according to the strength of evidence that supports the use or nonuse of antimicrobial prophylaxis:

Category A: levels I-III

Category B: levels IV-VI

Category C: level VII

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Postoperative infections (i.e., initial infection following surgical procedures)

Guideline Category

Assessment of Therapeutic Effectiveness

Prevention

Clinical Specialty

Anesthesiology

Colon and Rectal Surgery

Gastroenterology

Internal Medicine

Nephrology

Neurological Surgery

Obstetrics and Gynecology

Ophthalmology

Orthopedic Surgery

Otolaryngology

Pediatrics

Pharmacology

Plastic Surgery

Preventive Medicine

Surgery

Thoracic Surgery

Urology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Hospitals

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

- To provide practitioners with a standardized approach to the rational, safe, and effective use of antimicrobial agents for the prevention of surgical-site infections (SSIs) based on currently available clinical evidence and emerging issues
- To revise previously published American Society of Health-System Pharmacists (ASHP) Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery (1999)

Target Population

Adult (age 19 years or older) and pediatric (age 1–18 years) patients

Note: These guidelines do not specifically address newborn (premature and full-term) infants. While the guidelines do not address all concerns for patients with renal or hepatic dysfunction, antimicrobial prophylaxis often does not need to be modified for these patients when given as a single preoperative dose before surgical incision.

Interventions and Practices Considered

Primary antimicrobial prophylaxis (i.e., prevention of an initial infection) for surgical procedures, including antibiotic choice, dose, and dosage regimen

Major Outcomes Considered

- Postoperative infection rates
- Postoperative morbidity and mortality rates
- Duration and cost of health care
- Adverse effects

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The primary literature from the previous American Society of Health-System Pharmacists (ASHP) Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery was reviewed together with the primary literature published between the date of the previous guidelines, 1999, and June 2010, identified by searches of MEDLINE, EMBASE, and the Cochrane Database of Systematic Reviews.

Published guidelines with recommendations by experts in a procedure area (e.g., American College of Obstetricians and Gynecologists [ACOG]) and noted general guidelines (e.g., Centers for Disease Control and Prevention [CDC], Scottish Intercollegiate Guidelines Network, *Medical Letter*, Surgical Infection Society [SIS], Society for Healthcare Epidemiology of America [SHEA], Infectious Diseases Society of America [IDSA]) were also considered.

Number of Source Documents

The number of source documents used to update these recommendations is over 1600.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The strength of evidence represents only support for or against prophylaxis and does not apply to the antimicrobial choice, dose, or dosage regimen. Studies supporting the recommendations for the use of an antimicrobial were classified as follows:

- Level I (evidence from large, well conducted, randomized, controlled clinical trials or a meta-analysis)
- Level II (evidence from small, well conducted, randomized, controlled clinical trials)
- Level III (evidence from well conducted cohort studies)
- Level IV (evidence from well conducted case-control studies)
- Level V (evidence from uncontrolled studies that were not well conducted)
- Level VI (conflicting evidence that tends to favor the recommendation)
- Level VII (expert opinion or data extrapolated from evidence for general principles and other procedures)

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Particular attention was paid to study design, with greatest credence given to randomized, controlled, double-blind studies. There is a limited number of adequately powered randomized controlled trials evaluating the efficacy of antimicrobial prophylaxis in surgical procedures. Guidelines development included consideration of the following characteristics: validity, reliability, clinical applicability, flexibility, clarity, and a multidisciplinary nature as consistent with the American Society of Health-Systems Pharmacists (ASHP)'s philosophy on therapeutic guidelines. The limitations of the evidence base are noted within each individual procedure section of the guidelines.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These guidelines were developed jointly by the American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS), and the Society for Healthcare Epidemiology of America (SHEA).

Members of ASHP, IDSA, SIS, and SHEA were appointed to serve on an expert panel established to ensure the validity, reliability, and utility of the revised guidelines. The work of the panel was facilitated by faculty of the University of Pittsburgh School of Pharmacy and University of Pittsburgh Medical Center Drug Use and Disease State Management Program who served as contract researchers and writers for the project.

The level of evidence system (see the "Rating Scheme for the Strength of the Evidence" field) has been used by the Agency for Healthcare Research and Quality, and ASHP, IDSA, SIS, and SHEA support it as an acceptable method for organizing strength of evidence for a variety of therapeutic or diagnostic recommendations. Each recommendation was categorized according to the strength of evidence that supports the use or nonuse of antimicrobial prophylaxis as category A (levels I–III), category B (levels IV–VI), or category C (level VII).

When higher-level data are not available, a category C recommendation represents a consensus of expert panel members based on their clinical experience, extrapolation from other procedures with similar microbial or other clinical features, and available published literature. In these cases, the expert panel also extrapolated general principles and evidence from other procedures. Some recommendations include alternative approaches in situations in which panel member opinions were divided.

Rating Scheme for the Strength of the Recommendations

Each recommendation was assigned a category corresponding to the strength of evidence that supports the use or nonuse of antimicrobial prophylaxis:

Category A: levels I–III

Category B: levels IV–VI

Category C: level VII

Cost Analysis

Cost Containment

Few pharmacoeconomic studies have addressed surgical antimicrobial prophylaxis; therefore, a cost-minimization approach was employed in developing these guidelines. The antimicrobial agent recommendations are based primarily on efficacy and safety. Individual institutions must consider their acquisition costs when implementing these guidelines. Additional cost savings may be realized through collaborative management by pharmacists and surgeons to select the most cost-effective agent and minimize or eliminate postoperative dosing. The use of standardized antimicrobial order sets, automatic stop-order programs, and educational initiatives has been shown to facilitate the adoption of guidelines for surgical antimicrobial prophylaxis.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafted documents for each surgical procedural section were reviewed by the expert panel and, once revised, were available for public comment

on the American Society of Health-System Pharmacists (ASHP) website. After additional revisions were made to address reviewer comments, the final document was approved by the expert panel and the boards of directors of the above named organizations.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Morris DL, Wilson SR, Pain J, Edwardson KF, Jones J, Strachan C, Slack R. A comparison of aztreonam/metronidazole and cefotaxime/metronidazole in elective colorectal surgery: antimicrobial prophylaxis must include gram-positive cover. *J Antimicrob Chemother.* 1990 Apr;25(4):673-8. [PubMed](#)

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field). The authors note there are few data on the use of surgical antimicrobial prophylaxis in the pediatric population. Nearly all pediatric recommendations are based on expert opinion.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Effective use of antimicrobials for surgical prophylaxis may:

- Prevent surgical-site infections (SSI)
- Prevent SSI-related morbidity and mortality
- Reduce the duration and cost of health care (when the costs associated with the management of SSI are considered, the cost-effectiveness of prophylaxis becomes evident)

Potential Harms

- The use of antimicrobials for prophylaxis is associated with the risk of contributing to the development of antimicrobial resistance.
- A full discussion of the safety profile, including adverse events, drug interactions, contraindications, and warnings, for each antimicrobial agent is beyond the scope of these guidelines. Readers of these guidelines should review the U.S. Food and Drug Administration (FDA)-approved prescribing information and published data for specific antimicrobial agents before use.
- Fluoroquinolones are associated with an increased risk of tendonitis and tendon rupture in all ages. However, this risk would be expected to be quite small with single-dose antibiotic prophylaxis. Although the use of fluoroquinolones may be necessary for surgical antibiotic prophylaxis in some children, they are not drugs of first choice in the pediatric population due to an increased incidence of adverse events as compared with controls in some clinical trials.
- Ceftriaxone use should be limited to patients requiring antimicrobial treatment for acute cholecystitis or acute biliary tract infections which may not be determined prior to incision, not patients undergoing cholecystectomy for noninfected biliary conditions, including biliary colic or dyskinesia without infection.
- In one study, the adverse events of irritation and allergic reaction were experienced by three patients in the trimethoprim-polymyxin group.
- Second- and third-generation cephalosporins have not been shown to offer clear advantages over first-generation agents in hip fracture patients. These agents are not recommended for routine use due to their higher cost, potential to promote resistance, and association with adverse events (e.g., *C. difficile*-associated diarrhea).
- The use of aminoglycosides in combination with other nephrotoxic drugs may result in renal dysfunction and should be avoided unless alternatives are contraindicated.
- In one study of patients undergoing septorhinoplasty, there was a higher rate of adverse events (nausea, diarrhea, skin rash, and pruritus) among the group receiving combination preoperative postoperative oral amoxicillin-clavulanate

compared with the group receiving only a preoperative dose ($p = 0.03$).

Contraindications

Contraindications

Although true type 1 (immunoglobulin E [IgE]-mediated) cross-allergic reactions between penicillins, cephalosporins, and carbapenems are uncommon, cephalosporins and carbapenems should not be used for surgical prophylaxis in patients with documented or presumed IgE-mediated penicillin allergy.

Qualifying Statements

Qualifying Statements

- The recommendations herein may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the judgment of the clinician and consideration of individual patient circumstances and available resources.
- These guidelines reflect current knowledge of antimicrobial prophylaxis in surgery. Given the dynamic nature of scientific information and technology, periodic review, updating, and revisions are to be expected.
- The selection of an appropriate antimicrobial agent for a specific patient should take into account the characteristics of the ideal agent, the comparative efficacy of the antimicrobial agent for the procedure, the safety profile, and the patient's medication allergies. A full discussion of the safety profile, including adverse events, drug interactions, contraindications, and warnings, for each antimicrobial agent is beyond the scope of these guidelines. Readers of these guidelines should review the Food and Drug Administration (FDA)-approved prescribing information and published data for specific antimicrobial agents before use.
- In most cases, the data in pediatric patients are limited and have been extrapolated from adult data.
- A major limitation of the available literature on antimicrobial prophylaxis is the difficulty in establishing significant differences in efficacy between prophylactic antimicrobial agents and controls (including placebo, no treatment, or other antimicrobial agents) due to study design and low surgical-site infection (SSI) rates for most procedures.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Bratzler DW, Dellinger EP, Olsen KM, Perl TM, Auwaerter PG, Bolon MK, Fish DN, Napolitano LM, Sawyer RG, Slain D, Steinberg JP, Weinstein RA. Clinical practice guidelines for antimicrobial prophylaxis in surgery. *Am J Health Syst Pharm*. 2013 Feb 1;70(3):195-283. [1075 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 Sep 15 (revised 2013 Feb 1)

Guideline Developer(s)

American Society of Health-System Pharmacists - Professional Association

Infectious Diseases Society of America - Medical Specialty Society

Society for Healthcare Epidemiology of America - Professional Association

Surgical Infection Society - Professional Association

Source(s) of Funding

Financial support for the development of these recommendations was provided by the American Society of Health-System Pharmacists, Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, and the Surgical Infection Society.

Guideline Committee

Expert Panel

Composition of Group That Authored the Guideline

Authors: Dale W. Bratzler, D.O., M.P.H., Professor and Associate Dean, College of Public Health, and Professor, College of Medicine, Oklahoma University Health Sciences Center, Oklahoma City; E. Patchen Dellinger, M.D., Professor and Vice Chairman, Department of Surgery, and Chief, Division of General Surgery, University of Washington, Seattle; Keith M. Olsen, Pharm.D., FCCP, FCCM, Professor of Pharmacy Practice, Nebraska Medical Center, Omaha; Trish M. Perl, M.D., M.Sc., Professor of Medicine, Pathology, and Epidemiology, Johns Hopkins University (JHU), and Senior Epidemiologist, The Johns Hopkins Health System, Baltimore, MD; Paul G. Auwaerter, M.D., Clinical Director and Associate Professor, Division of Infectious Diseases, School of Medicine, JHU; Maureen K. Bolon, M.D., M.S., Associate Professor of Medicine, Division of Infectious Diseases, Feinberg School of Medicine, Northwestern University, Chicago, IL; Douglas N. Fish, Pharm.D., FCCM, FCCP, BCPS, is Professor and Chair, Department of Clinical Pharmacy, University of Colorado, Anschutz Medical Campus, and Clinical Specialist, Critical Care/Infectious Diseases, Department of Pharmacy Services, University of Colorado Hospital, Aurora; Lena M. Napolitano, M.D., FACS, FCCP, FCCM, Professor of Surgery and Division Chief, Acute Care Surgery, Trauma, Burn, Critical Care, Emergency Surgery, and Associate Chair of Surgery, Critical Care, Department of Surgery, and Director, Surgical Critical Care, University of Michigan Health System, Ann Arbor; Robert G. Sawyer, M.D., FACS, FIDSA, FCCM, Professor of Surgery, Public Health Sciences, and Chief, Division of Acute Care, Surgery and Outcomes Research, University of Virginia Health System, Charlottesville, VA; Douglas Slain,

Pharm.D., BCPS, FCCP, FASHP, Associate Professor of Pharmacy and Medicine, West Virginia University, Morgantown; James P. Steinberg, M.D., Professor of Medicine, Division of Infectious Diseases, Emory University, Atlanta, GA; Robert A. Weinstein, M.D., C. Anderson Hedberg MD Professor of Internal Medicine, Rush Medical College, Chicago, and Chairman, Department of Medicine, Cook County Health and Hospital System, Chicago

Financial Disclosures/Conflicts of Interest

Panel members and contractors were required to disclose any possible conflicts of interest before their appointment and throughout the guideline development process.

Dr. Bratzler is a consultant for Telligen; Dr. Dellinger has received honoraria for participation on advisory boards and consultation for Merck, Baxter, Ortho-McNeil, Targanta, Schering-Plough, WebEx, Astellas, Durata, Pfizer, Applied Medical, Rib-X, 3M, the American Hospital Association, Premier Inc., Oklahoma Foundation for Medical Quality, and the Hospital Association of New York State; Dr. Perl serves on the advisory boards of Hospira and Pfizer and has received a grant from Merck; Dr. Auwaerter serves on the advisory panel of Genentech; Dr. Fish serves on the advisory board and speakers' bureau of Merck; and Dr. Sawyer serves as a consultant for Pfizer, Merck, Wyeth, 3M, and Ethicon and has received an R01 grant from the National Institute of General Medical Sciences and a T32 grant from the National Institute of Allergy and Infectious Diseases. Drs. Bolon, Napolitano, Olsen, Steinberg, Slain, and Weinstein have declared no potential conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Society of Health-System Pharmacists. ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999 Sep 15;56(18):1839-88.

Guideline Availability

Electronic copies: Available from the [American Society of Health-System Pharmacists \(ASHP\) Web site](#) .

Print copies: Available from the American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814.

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This summary was completed by ECRI on April 10, 2000. It was verified by the guideline developer on August 4, 2000. This NGC summary was updated by ECRI Institute on April 8, 2013. The updated information was verified by the guideline developer on May 6, 2013. This summary was updated by ECRI Institute on October 25, 2013 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs. This summary was updated by ECRI Institute on March 6, 2014 following the U.S. Food and Drug Administration advisory on Over-the-Counter Topical Antiseptic Products. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouse^{â„¢} (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the [NGC Inclusion Criteria](#).

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.